

TO: WHOM IT MAY CONCERN
FROM: MARY GIDARO
SUBJECT: FDA MODERNIZATION ACT OF 1997
DATE: 5 JUNE 1998
CC: DR. JOSEPH SCHERZER

2333 '98 JUN 18 P12:31

I am writing on behalf of Dr. Joseph Scherzer. I am a patient of the doctor and feel the restrictions put on doctors who are currently compounding and prescribing ingredients or a combination of ingredients they feel meet their patients needs are taking away why they treat us in the first place. They can better prescribe the medicine at a better cost and give us specifically what we need. I am against these restrictions to no longer make it available to provide us this service.

Thank you,

Mary T. Gidaro

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Sales Support Manager



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JOSEPH M. SCHERZER, M.D.

Diplomate of the American Board of Dermatology
Diplomate of the American Board of Dermatopathology

Food and Drug Administration
Dockets Management Branch (HFA-305)
12420 Parklawn Dr., Room 1-23
Rockville, Maryland 20857
June 3, 1998

Re: Section 503(A), FDA Modernization Act of 1997
Docket No. 98N-0182

To Whom It May Concern:

Having just learned of this act, and of an imminent deadline concerning same, I wish to nominate two vehicles I am using to compound several forms of retinoic acid for my patients.

I am compounding three different strengths of a retinoic acid cream (0.025%, 0.05%, and 0.1%) and two different strengths of a retinoic acid gel, using Cream Base R from C & M Pharmacal for the cream, and a gel base for the gels. these are ued topically only, for acne, and comedones.

Pursuant to section 503(A), (a)(2)(A), I am a licensed physician in active private practice in Arizona, compounding these products in limited quantities before the receipt of a valid prescription order for individual patients, and (B) also based on my history as such a licensed physician having received many prescription requests for all of these products over many years by my patients, who are the only individuals for whom I prescribe such products (B)(ii)(I).

Regarding 503(A)(b)(2) [Definition], I am using drug products which represent a change made for my aforementioned patients which produces for those patients a significant difference, as determined by myself, between the compounded drug and commercially available drug product. Here is the information you require about the bulk drug substances I am using:

I am using (as a main ingredient) retinoic acid (tretinoin), USP chemical grade, supplied to me in crystalline form. As far as bibliographical information concerning its safety and efficacy, I would refer you to Ortho's Retin A NDA

I formulate 0.025%, 0.05% and 0.1% cream forms of this, and 0.01% and 0.025% gel forms - all topical preparations.

The cream base R supplied by C&M Pharmacal, unlike Retin A, has no isopropyl myristate, avoiding a potential irritant. Unlike Renova, the base has no Mineral oil, thus avoiding potential comedogenicity. Also, unlike Renova, I can provide two other strengths of retinoic acid in a cream base, and offer better therapeutic effects for my patient population. Many of my patients who request a Renova-like product are younger, rather than older patients, and either prone to acne or currently being treated for it. Renova would not be appropriate here. (Johnson and

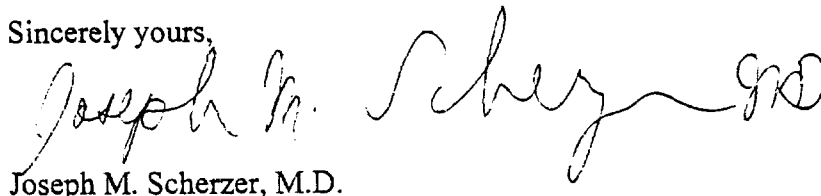
Johnson makes no claim whatsoever that Renova is safe for acne, while the other brand name of 0.05% retinoic acid, Retin A, is marketed directly for acne.)

As far as the gel base is concerned, it also offers advantages. Retin A uses specially denatured ethyl alcohol, while C&M uses isopropyl alcohol. Retin A (Ortho) uses hydroxypropylcellulose as a gellant while C&M uses Carbomer 940. I prefer C&M's agents; the final product is smoother, and has had great patient acceptance.

I am using these cream and gel bases for the sole purpose of compounding these tretinoin formulations I have just described.

There are many examples in dermatology of the importance of specific bases, which can make all the difference in the world to patients. The selection of such should be left to the individual practitioner. For example, if I prescribe Aristocort A cream for my patients with a dry skin condition called eczema (atopic dermatitis), I will help them by use of its moisturizing base. If I permit a generic substitution (which many formularies are now demanding), my patients can well wind up with the same active ingredient formulated in a drying, desiccating vehicle, which can dry out their skin and make their eczema worse instead of better. We need to be able to do what we are trained to do, for the best interests of the patients and the profession as a whole.

Sincerely yours,

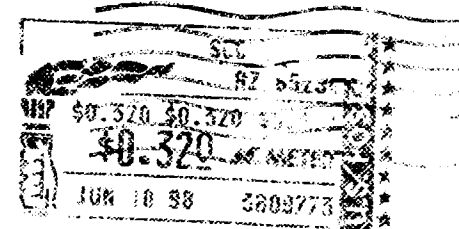
A handwritten signature in cursive script, reading "Joseph M. Scherzer" followed by a stylized "MD".

Joseph M. Scherzer, M.D.

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